

Customer No. 28596
Attorney Docket No.: MP/84

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Campbell et al.

Serial No.: 08/499,423

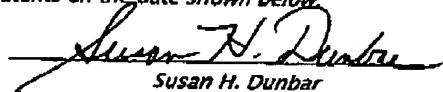
Filed: July 7, 1995

For: Interior Liner for Tubes, Pipes and
Blood Conduits

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

) Group Art Unit: 3738
) Examiner: Brian E. Pellegrino
)

*I hereby certify that this correspondence is being
facsimile transmitted to the Commissioner for
Patents on the date shown below:*


Susan H. Dunbar

06/08/06
(date of faxing document)

DECLARATION OF WAYNE D. HOUSE

1. I, Wayne D. House, am not an inventor of the above referenced U.S. Patent Application Serial No. 08/499,423.

2. I am a registered practitioner (No. 34,623) and have previously prosecuted this application.

3. I am familiar with the teachings of the U.S. Patent 5,641,373 by Shannon et al. filed April 17, 1995, hereinafter referred to as Shannon et al.

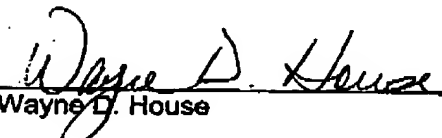
4. Shannon et al. describe methods of manufacturing radially enlargeable tubular tape-reinforced polytetrafluoroethylene (PTFE) grafts.

5. The invention (referenced above) teaches an interior liner for tubes, pipes and blood conduits comprising a tubular form circumferentially distensible and conformable whereby the first circumference of the interior liner may be distended by the application of pressure causing the first circumference to be increased to a larger circumference. It is taught that for applications relating to use as a liner for blood conduits, it is preferred that the interior liner have a second circumference beyond which it is not readily distensible.

6. I wrote a laboratory notebook entry describing and corroborating David J. Myers work based on his verbal description to me of the work performed, as shown on the attached notebook pages (Exhibit A). I was not otherwise personally involved in this work. Although the dates have been redacted from these notebook pages, this work was performed prior to April 16, 1994.

7. According to the laboratory protocol notebook (Exhibit A), the first radially expandable film tube of the present invention was made prior to the filing date of Shannon et al. This successful experiment demonstrated the method of making a thin-wall film tube of a small diameter that increased to a pre-determined limited larger diameter by the application of force.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.


Wayne D. House

6 JUNE 2006
Date

DATE

SUBJECT OF EXPT. RADIALY EXPANDABLE (i.e. DIAMETRICALLY ADJUSTABLE) FILM TUBE

A FILM TUBE WAS MADE BY FIRST WRAPPING AN 8mm DIA S.S. MANDREL WITH A SINGLE LAYER OF CONVENTIONAL V.C. FILM APPLIED IN A CIGARETTE-WRAP FASHION (FIBERS ORIENTED LONGITUDINALLY). TWO NARROW TAPES WERE USED, EACH TAPE COVERING 180° OF THE MANDREL SURFACE. THE EDGES WERE TRIMMED AND SEALED BY THE CONVENTIONAL CIGARETTE-WRAP METHOD USED FOR VASCULAR GRAFT REMOVABLE RING FILM.

AFTER THIS LONGITUDINALLY-ORIENTED LAYER OF FILM WAS APPLIED AROUND THE SURFACE OF THE MANDREL, ANOTHER LAYER OF EPTFE FILM (TAPE) WAS HELICALLY WRAPPED ABOUT THIS FIRST LAYER USING A SEVERE BIAS ANGLE OF ABOUT 20° WITH RESPECT TO THE LONGITUDINAL AXIS OF THE MANDREL. THE FILM (TAPE) USED WAS ONE INCH WIDE; THE SEVERE BIAS ANGLE LEFT A RELATIVELY WIDE GAP BETWEEN ADJACENT LAPS OF THE HELICAL WRAP. A ~~THIRD~~ SECOND LAYER OF HELICAL WRAP WAS APPLIED AT THE SAME ANGLE TO COVER THIS GAP. THE EDGES OF THESE FIRST & SECOND HELICAL LAYERS OVERLAPPED BY AN AMOUNT VARYING FROM ABOUT 1-5mm. THE FILM USED FOR THE HELICAL WRAPPING WAS A DISCONTINUOUS (POROUS) BACING FILM OF EPTFE HAVING AN ADHESIVE ON ONLY ONE SIDE WHICH WAS THE SIDE APPLIED AGAINST THE FIRST, LONGITUDINALLY-ORIENTED LAYER OF FILM.

AFTER HELICAL WRAPPING THE FILM-WRAPPED MANDREL WAS PLACED INTO AN AIR CONVECTION OVEN SET AT 380°C FOR 20 MINUTES, REMOVED FROM THE OVEN & ALLOWED TO COOL. THE FILM TUBE WAS THEN REMOVED FROM THE 8mm MANDREL. THE FINISHED LENGTH OF THIS TUBE WAS 33cm WITH A WALL THICKNESS (SINGLE WALL) OF ABOUT 0.025-0.03mm (CALIBERS).

NEXT, THE FILM TUBE WAS FITTED ONTO THE SMALL END OF AN 18cm LONG DELTA MANDREL THAT TAPERED FROM A 6.5mm DIA. TO ON ONE END TO A 12mm DIA. ON THE OTHER. THE TUBE WAS EXPANDED (INCREASED IN DIAMETER) BY PUSHING IT ALONG THE LENGTH OF THE MANDREL TOWARD THE LARGER DIA END OF THE MANDREL. THE TUBE WAS RELATIVELY EASY TO EXPAND DIAMETRICALLY IN THIS MANNER; HOWEVER IT DID FEEL AS THOUGH IT DID NOT WANT TO EXPAND MUCH BEYOND THE 12mm DIAMETER. THE DIAMETER INCREASE OCCURRED WITH A DECREASE IN LENGTH TO ABOUT 28cm & WITH AN INCREASE IN THE BIAS ANGLE OF THE HELICALLY-WRAPPED FILM TO ABOUT 45°. THE LONGITUDINAL SEAMLINES OF THE LONGITUDINALLY-ORIENTED FILM LAYER HAD ASSUMED A BIAS ANGLE OF ABOUT 20° WITH RESPECT TO THE LONGITUDINAL AXIS OF THE TUBE.

(CONT.)

EXPERIMENTER

Wayne House

WITNESS

Edward A. Kuhl

DATE

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SUBJECT OF EXPT. (CONT.)

WITH THIS CONSTRUCTION METHOD IT APPEARS POSSIBLE TO MAKE A THIN-WALL FILM TUBE OF A SMALL DIAMETER THAT MAY BE INCREASED TO A PRE-DETERMINED LIMITED LARGER DIAMETER BY THE APPLICATION OF FORCE FROM, FOR EXAMPLE, A BALLOON CATHETER. SMALL AMOUNTS OF FORCE MAY ALSO PROVE TO BE ENOUGH. POSSIBLY BLOOD PRESSURE ALONE. A TUBE OF THIS TYPE MAY THEREFORE BE USEFUL AS AN INTRA-LUMINAL GRAFT, WITH OR WITHOUT THE USE OF EXPANDABLE METAL STENTS. THE IDEA FOR THIS TUBE CAME FROM DAVID MYERS; THE TUBE WAS MADE BY CLAYTON SPARKLING. CLAYTON SUGGESTED THE USE OF THE RELATIVELY WIDE (1") FILM FOR THE HELICAL WRAP.

EXPERIMENTER

WITNESS

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